

### **REMARKS**

Applicants respectfully request further examination and reconsideration in view of the above amendment and the arguments set forth fully below. In the Office Action mailed April 26, 2006, claims 1-25 have been rejected. In response, the Applicants have submitted the following remarks, amended claims 1, 9, 12 and 17, and cancelled claims 5, 8, 16 and 25. Accordingly, claims 1-4, 6-7, 9-15 and 17-24 are now pending. Favorable reconsideration is respectfully requested in view of the amended claims and remarks below.

#### **Rejections Under 35 U.S.C. §112**

Claims 5 and 12 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Within the Office Action, it is specifically stated that claim 5 is redundant of claim 1, and that claim 5 should be deleted. In response, the Applicants have cancelled claim 5. Furthermore, it is specifically stated in the Office Action that in claim 12, line 3 "the analysis" lacks antecedent basis. By the above amendment, the Applicants have amended claim 12 to include the word "module" behind "the analysis," wherein "the analysis module" does indeed include proper antecedent basis. For at least these reasons, claims 5 and 12 are allowable as definite under 35 U.S.C. §112.

#### **Rejections Under 35 U.S.C. §103**

Claims 1-6, 9-13 and 17-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,876,351 to Rohde (hereinafter Rohde) in view of U.S. Patent No. 5,967,994 to Wang (hereinafter Wang). It should be noted that the dependent claims 8, 16 and 25, which previously depended upon the independent claims 1, 9 and 17, have been cancelled, and those limitations have been amended into the independent claims 1, 9 and 17 respectively. The rejections of the cancelled claims 8, 16

and 25 further included the combination of Rohde, Wang and further in view of U.S. Patent No, 6,238, 338 to DeLuca et al. (hereinafter DeLuca). The Applicants will hereby review the allowability of the independent claims 1, 9, and 17 in light of Rohde, Wang and DeLuca in combination.

Rohde teaches a portable modular diagnostic medical device based on a portable multi-purpose platform such as a portable game system used by children to play video games. The portable medical device includes a ECG cartridge having lead connected to a patient and further configured to plug as one unit into the portable medical device. Within the Office Action it is stated that the functionality of the monitoring device can be expanded or potentially expanded, such as adding the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts. However, the applicants respectfully submit that nowhere in the Rohde reference is it taught, or even suggested, that the portable medical device of Rohde may be expanded to include such functionality. Furthermore, it is recognized in the Office Action that Rohde does not teach these functionalities, nor an analysis module including a processor and software.

Wang teaches a method and system for characterizing the quality of signals inductive of heart function, wherein the signals in Wang are combined, and analyzed for noise quality. However, Wang does not teach an instrumentation amplifier that is configured to filter the ECG signals, combine the signals to generate a multi-lead ECG, and an analog-digital converter, that allows the multi-lead ECG to be converted to a digital signal and analyzed as a single digital signal for cyclic artifact.

DeLuca teaches a bio-signal monitoring system and method which includes an analog to digital converter. While the DeLuca reference teaches the ability to convert an ECG signal to a digital signal, it fails to teach converting a multi-lead ECG signal into a multi-lead digital ECG signal for analysis to detect cyclic artifact.

The Applicants further submit that there is no teaching in any of the references for them to be combined. Applicants respectfully suggest that in the outstanding action the rejections evidence "picking and choosing" features of various references and combining

them when there is no suggestion in those references to do so. It is impermissible within the framework of a 35 U.S.C. §103 rejection to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. Furthermore, obviousness cannot be established by combining the teachings of prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. Teachings of references can only be combined if there is some suggestion or incentive to do so. Again, none of these references, whether cited or of record, taken either alone or in combination, disclose or suggest the invention as now recited.

Furthermore, where the Examiner relies upon three or more references in support of a single rejection, the multiplicity of references supports the Applicants' assertion of non-obviousness, because even with knowledge of the Applicants' structure, the Examiner had to rely on not one or two, but three reference, and pick and choose among the features of those references to come up with the elements of the claimed invention. But for the knowledge of Applicants' structure, gleaned from reading the application, it is not likely that the Examiner or another skilled in the art would have thought of picking one part from one reference, one part from another, and still more from another. None skilled in the art, so far as the patents cited by the Examiner are concerned, thought of making this combination as evidence from the multiplicity of references that are necessary to make the rejection. Furthermore, it is stressed that none of the references, even in combination, teach analyzing a multi-lead digital ECG signal to detect cyclic artifact.

Lastly, the Applicants respectfully submit that the age of the cited references indicates a lack of some teaching or suggestion supporting the combination. The Rohde Patent issued on March 2, 1999, the Wang Patent issued on October 19, 1999, and the DeLuca patent issued on May 29, 2001. The present application was filed on January 14, 2004, almost three years after DeLuca issued. The Applicants respectfully submit that if

the combination of the cited references was obvious, as is stated in the Office Action, then it is probable that such a combination would have been made prior to the filing of the present application. Therefore, the Applicants submit that this combination of references is indeed not obvious.

The independent claim 1 is directed to a medical device for acquiring and analyzing a multi-lead electrocardiogram comprising an input terminal for connection to a patient to acquire multi-lead ECG signals from the patients, an instrumentation amplifier connected to the input terminal to filter the ECG signals and combine the signals to generate a multi-lead ECG, an analysis module including a processor and software for operating the processor to detect cyclic artifact in the multi-lead ECG and select a lead for analysis based on a lack of cyclic artifact in that lead, and an analog to digital converter connected between the instrumentation amplifier and the analysis module, wherein the multi-lead ECG generated by the instrumentation amplifier is an analog multi-lead ECG, where the analog to digital converter converts an analog multi-lead ECG to a digital multi-lead ECG and wherein the analysis module detects cyclic artifact in the digital multi-lead ECG. As discussed above, neither Rohde, Wang, DeLuca nor their combination teach analyzing a digital multi-lead ECG signal for cyclic artifact. For at least these reasons, the independent claim 1 is allowable over the teachings of Rohde, Wang, DeLuca and their combination. For the same reasons, the Applicants respectfully submit that the independent claims 9 and 17 are also allowable over the teachings of Rohde, Wang, DeLuca and their combination.

Claims 2-4, 10-13 and 18-23 are dependent upon the independent claims 1, 9, and 17. As discussed above, the independent claims 1, 9, and 17 are allowable over the teachings of Rohde, Wang, DeLuca and their combination. Accordingly, claims 2-4, 10-13 and 18-23 are also allowable as being dependent upon an allowable base claim. Claim 5 has been cancelled.

Claims 7, 15 and 24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rohde in view of Wang, and further in view of U.S. Patent No.

6,119,035 also to Wang. Claims 7, 15 and 24 are dependent upon the independent claims 1, 9, and 17. As discussed above, the independent claims 1, 9 and 17 are allowable over the teachings of Rohde, Wang, DeLuca and their combination. Accordingly, claims 7, 15 and 24 are also allowable as being dependent upon an allowable base claim.

*Specification Objections*

The specification has been objected to because within the Office Action it is stated that on page 5, line 22, it appears "Figure 2" should "Figure 3." However, the Applicants respectfully submit that the occurrence of "Fig. 2" on line 22 is appropriate, but the occurrence of "Fig. 2" on line 23 should indeed be corrected "Fig. 3." By the above amendment the Applicants have corrected the specification accordingly.

*Claim Objections*

Claim 25 has been objected to because within the Office Action it is stated that the sentence ends with two periods. However, the Applicants respectfully submit that nowhere in the file history does claim 25, nor any other claim, end with two periods. Therefore, the Applicants respectfully submit that the Examiner withdraw this objection to claim 25.

*Information Disclosure Statement*

Within the Office Action it is stated that the Information Disclosure Statement filed January 14, 2004 fails to comply with 37 C.F.R. 1.98(a)(2), which requires a legible copy of each cited foreign patent document, each non-patent literature publication or that portion which caused it to be listed, and all other information or that portion which caused it to be listed. The two non-patent literature publications noted in the Information Disclosure Statement, the article Kaiser and the article by Van Alste apparently were not submitted, hence they have not been considered.

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In response, the Applicants will subsequently submit these two listed non-patent publications under separate cover.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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